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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,310	10/10/2000	Kurt Haas	1079-2	3443

7590 02/15/2002

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EXAMINER

LEWIS, MICHELLE A

ART UNIT PAPER NUMBER

3763

DATE MAILED: 02/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/685,310

Applicant(s)

HAAS ET AL.

Examiner

Michelle A Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: _____

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DETAILED ACTION

Drawings

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81.

No new matter may be introduced in the required drawing.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the electroporation assembly must be shown or the features canceled from the claims. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The "tissue support" was not thoroughly described in the claims or specification, neither was there any picture of it.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The phrase "diameter less than the diameter of a target cell" in claims 4 and 12 is a relative term which renders the claim indefinite. There has not been provided a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The following assessment has been made of the apparatus and method as best understood by Examiner:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dev et al and further in view of Weaver et al., Atkins et al (IDS), and Teruel et al. (IDS). Dev discloses a housed tubular body that has a distal opening, a center needle, which acts as one electrode partially disposed within the tubular body. It also discloses an embodiment where the container is that of a syringe. The device is attached to a power supply, in the form of a pulse generator, which can supply, among other types, a square pulse signal (low or high frequency), or an exponential decay pulse. This invention also includes an annular arrangement that acts as another electrode. (See column 3 line 42 – column 4 line 38, column 6 lines 25-33, column 7 lines 1-9) Dev shows that it is known in the art to use electroporation to introduce nucleotide sequences

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into mammalian cells. It is also mentioned that this process can be done in vivo and also have similar amplitude requirements for being done in vitro. (See column 2 lines 15-17, column 6 line 52 - column 7 line 22)

Dev did not disclose the container from the selected group being a micropipette. It is silent concerning the type of cells that the substances can be deliver to. Dev is also silent concerning the specific conductive material used to make the electrodes, as well as specific dyes and proteins used in this method.

In analogous art, Weaver et al. disclose a housed reservoir device, which contains fluid composition, and uses electrodes connected to a pulse configured power source. (See column 3line64 – column 4 line 23) Weaver shows the electrodes most suitable are made from conductive materials such as “copper, gold, aluminum etc...”. The fluid composition in the container’s reservoir is also more specific, it is taught to be electrically conductive. (See column 5 lines 5-32) An optical indicator bead is also recommended as a suitable form of measuring. (See column 8 lines14-23)

Atkins shows use of a glass pulled micropipette as the apparatus of choice to conduct experiments using the method of electroporation. [See Vol. 28 No.1 (2000) Biotechniques “Material and Methods”] Therefore it was known to the inventors at the time that the invention was made that this was an effective tool in the art.

Teruel et al. teaches molecular techniques, including electroporation using cells of the central nervous system. This reference also discusses use of the green fluorescent protein, as well as other indicators. [See Vol. 93 (1999) Journal of Neuroscience “A versatile microporation technique for the transfection of cultured CNS neurons”]

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One of ordinary skill in the art would be well aware of the techniques of electroporation, including the effectiveness of using dyes and colored proteins and also the commonly used tools, such as a pipette and various derivatives. Therefore to one of ordinary skill in the art at the time of the invention, knowing common industry practices, it would have been obvious to modify the device and methods of Dev et al, with the specifics of Weaver in order to produce the simplest, yet effective apparatus and method for electroporation.

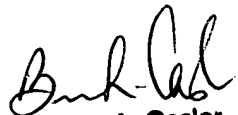
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle A Lewis whose telephone number is (703) 305-0842. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

January 31, 2002


Brian L. Casler
Primary Examiner